

Safety Data Sheet
according to WHS Regulations

Printing date 12.12.2019

Version number 2


Revision: 12.12.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name:** ***Variolink Esthetic DC (Base)***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dual-curing resin-based dental luting material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60
- **Importer:**
Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
 - **Label elements**
 - **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
 - **Hazard pictograms**
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GHS07
- **Signal word** Warning
 - **Hazard-determining components of labelling:**
urethane dimethacrylate
acetyl-2-thiourea
1,10-decandiol dimethacrylate
2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol

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- **Hazard statements**

Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.

- **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Wash contaminated clothing before reuse.
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	10-25%
CAS: 72869-86-4	urethane dimethacrylate Eye Irrit. 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate Eye Irrit. 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 2440-22-4	2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol Skin Sens. 1, H317	<2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **Description of first aid measures**

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:**

Rinse with water.
If skin irritation continues, consult a doctor.

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

- **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Keep away from foodstuffs, beverages and feed.

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Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:** Not required.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

After use of gloves apply skin-cleaning agents and skin cosmetics.

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye protection:** Safety glasses

9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Pasty

Colour: According to product specification

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapour pressure:** Not applicable.

· **Density at 20 °C:** 1.8567 g/cm³

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

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- | | |
|--|--|
| · Solubility in / Miscibility with water: | Nearly insoluble. |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| · Dynamic: | Not applicable. |
| · Kinematic: | Not applicable. |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** Irritant to skin and mucous membranes.
- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|--|
| · UN-Number
· ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADG, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADG, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Australian Inventory of Chemical Substances**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

- **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

- **Hazard pictograms**



GHS07

- **Signal word** Warning

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- urethane dimethacrylate

- acetyl-2-thiourea

- 1,10-decandiol dimethacrylate

- 2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol

- **Hazard statements**

- Causes skin irritation.

- Causes serious eye irritation.

- May cause an allergic skin reaction.

- May cause respiratory irritation.

- **Precautionary statements**

- Wear protective gloves/protective clothing/eye protection/face protection.

- If skin irritation or rash occurs: Get medical advice/attention.

- If eye irritation persists: Get medical advice/attention.

- Wash contaminated clothing before reuse.

- Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

- The product is a medical device according to the Directive 93/42/EEC.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

- H315 Causes skin irritation.

- H317 May cause an allergic skin reaction.

- H319 Causes serious eye irritation.

- H335 May cause respiratory irritation.

- **Abbreviations and acronyms:**

- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

- IMDG: International Maritime Code for Dangerous Goods

- IATA: International Air Transport Association

- EINECS: European Inventory of Existing Commercial Chemical Substances

- ELINCS: European List of Notified Chemical Substances

- CAS: Chemical Abstracts Service (division of the American Chemical Society)

- PBT: Persistent, Bioaccumulative and Toxic

- vPvB: very Persistent and very Bioaccumulative

- Skin Irrit. 2: Skin corrosion/irritation – Category 2

- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

- Skin Sens. 1: Skin sensitisation – Category 1

- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3